UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,709	08/22/2001	Charles A. Morris	1533.0520001	6249

41835 7590 09/14/2010

K&L GATES LLP
210 SIXTH AVENUE
PITTSBURGH, PA 15222-2613

EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHARLES A. MORRIS,
FRANCIS W. CALHOON, JR., and
HUEY L. WILLIS

Appeal 2009-015190
Application 09/933,709
Technology Center 1600

Before MICHAEL P. COLAIANNI, ERIC GRIMES, and
BEVERLY A. FRANKLIN, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

---

[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

Appellants appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 18-24, 26-44, and 47-51. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 18, 22, and 23 are representative of the subject matter on appeal and are set forth below:

18. A free-flowing composition comprising:

about 5 to about 34 weight percent redried cornstarch;

silica having a particle size of between 40 and 50 microns; and

65 to 80 weight percent of at least one fat soluble vitamin.

22. A free flowing composition comprising:

about 5 to about 34 weight percent starch;

silica having a density of at least 12.5 lbs./cu.ft., a particle size of between 40 and 50 microns, and a surface area of from about 400m^2/g to 500 m^2/g; and

at least 65 to 80 weight percent of at least one fat soluble vitamin.

23. The composition of claim 22, wherein the at least one vitamin is selected from the group comprising vitamin A, vitamin D, vitamin E, vitamin K, vitamin C, vitamin B_3 and vitamin B_5.

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Drake	4,010,073	Mar. 1, 1977
Schmidt ('435)	4,486,435	Dec. 4, 1984
Schmidt ('143)	4,603,143	Jul. 29, 1986
Rawlins	4,719,228	Jan. 12, 1988

THE REJECTIONS

1. Claim 23 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claims 18-24, 26-44, and 47-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Schmidt '435 in combination with Schmidt '143 and Rawlins or Rawlins in view of Schmidt '435 or Schmidt '143 by themselves or in combination.

3. Claims 18-24, 26-44, and 47-51 are rejected under 35 U.S.C.§ 103(a) as being unpatentable over Schmidt '435 in combination with Schmidt '143 and Rawlins or Rawlins in view of Schmidt '435 or Schmidt '143 by themselves or in combination, further in view of Drake.

ANALYSIS
(with Findings of Fact and Principles of Law)

1. The Rejection of claim 23 under 35 U.S.C. § 112, second paragraph, as being indefinite

The Examiner indicates that claim 22 recites "fat soluble vitamin"; yet dependent claim 23 includes B vitamins, which are hydrophilic and not fat soluble vitamins. Ans. 2.

On page 5 of the Brief, Appellants indicate that claim 23 has been amended to recite a grouping of fat soluble vitamins. However, it appears from the Advisory Action mailed on October 3, 2007, that this amendment was not entered.

Therefore, this rejection is affirmed. Upon return of this application to the jurisdiction of the Examiner, we call upon the Examiner and Appellants to resolve this issue.

2. The Rejection of claims 18-24, 26-44 and 47-51 under 35 U.S.C. § 103(a) as being unpatentable over Schmidt '435 in combination with Schmidt '143 and Rawlins or Rawlins in view of Schmidt '435 or Schmidt '143 by themselves or in combination

The teachings of the applied art as compared with the subject matter of claim 18 are best summarized in the following table.

Claim 18	Schmidt '435	Schmidt '143	Rawlins	Drake
about to 5 about 34 wt % redried cornstach	2 to 8 wt% cornstarch			Redried cornstarch
silica having a particle size of between 40 and 50 microns	about 0.2 to about 2.0 wt% silica	Silica having a particle size of 300 microns	Silica having a particle size of at least 10 microns, preferably from 10 microns to 1 mm, and Example 2 teaches 50 microns	
65 to 80 wt % of at least one fat soluble vitamin	45 to 60 wt% of a fat soluble vitamin			

It is the Examiner's position that Schmidt '435's teachings of from 45 to 60 weight percent of a fat soluble vitamin would have rendered obvious Appellants' claimed amount of from 65 to 80 weight percent of a fat soluble vitamin. Ans. 9. We agree. A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of Am. v. Banner,* 778 F.2d 775, 782 (Fed. Cir. 1985).

It is also the Examiner's position that Rawlins' teaching of the particle size of silica as indicated in the above table would have rendered obvious Appellants' claimed particle size of silica of between 40 and 50 microns. Ans. 4-5.

In response, Appellants argue that while Rawlins teaches silica particles ranging from 10 microns to 1 mm (including Sipernat 50) in combination with a pharmaceutically active ingredient (i.e., indomethacin, ketazolam, diazepam, digoxin, and 6-cyano-3,4-dihydro-2,2-dimethyl-trans-4-(2-oxo-l-pur-rolidinyl)-2H-benzo[b]pyran-3-ol) that is free-flowing, Rawlins does not suggest combining silica with a fat soluble vitamin. Br. 7.

Appellants argue that, according to the Examiner, it would have been expected from reading Rawlins that all size ranges would work with fat

soluble vitamins, but, as the Declaration of Morris shows, only a relatively narrow range is actually suitable for maintaining free-flowability.[2] Br. 7.

Appellants conclude that thus without any direction or guidance, Rawlins cannot render obvious a silica particle size in the 40-50 micron range which maintains free-flowability when fat soluble vitamin is absorbed at the levels recited in claims 18, 22, 26, and 29 as well as the claims dependent thereon. Br. 7.

We agree with the Examiner's position on pages 4-5 of the Answer. Therein, the Examiner states:

> It would have been obvious to use the silica of bigger particle sizes 40-50 microns in the compositions of Schmidt et al 435 or 143 w*ith a reasonable expectation of success* [emphasis added], since as evidenced by Rawlins, one can obtain free-flowing powders using silica which has a diameter between 10 microns to 1 millimeter, in particular 50 microns. Although the references are silent with respect to the density and the surface area of the silica particles, since these are commercially available particles and in the absence of showing otherwise and the criticality of these factors, it is the position of the examiner that Rawlins's silica particles which were obtained commercially possess these properties or manipulatable parameters to obtain the best possible results.

We note that obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success can support a

[2] A more accurate description of the Examiner's position is that the particle size range taught in Rawlins suggests Appellants' claimed particle size range. Ans. 4.

conclusion of non-obviousness. *In re Rinehart*, 531 F.2d 1048, 1053-54 (CCPA 1976).

In the instant case, Appellants do not offer any evidence showing there was no reasonable expectation of success of obtaining free flowability by using the size range taught by Rawlins for the silica particles of Schmidt '435.

Schmidt '435 is directed to free flowing vitamin powders, wherein the loading density of the vitamin is as high at 60 weight percent, but is silent as to the size of the silica particles used in making the free flowing powder. Rawlins does give guidance as to the size of the silica particles to achieve free flowability in a pharmaceutical composition comprising a free flowing powder. Appellants have not convinced us that there would not be a reasonable expectation of success of using the particle size taught in Rawlins in the powder of Schmidt '435 in the context of a free flowing vitamin powder.

Appellants argue that the Morris Declaration shows that only the 40 to 50 micron range results in a free-flowing powder containing a high loading density of fat soluble vitamins. Br. 6. However, we cannot find data supporting this position, i.e., we find a particle size of 50 microns, but there is no data across the claimed range of between 40 and 50 microns. Hence, the Declaration is not commensurate in scope with the claims. The Examiner also discusses this fact. Ans. 7. For at least this reason, the Declaration is insufficient. When considering whether proffered evidence demonstrates patentability, a side-by-side comparison of the claimed

invention with the closest prior art which is commensurate in scope with the claims is needed, with an explanation as to why the results would have been unexpected by one of ordinary skill in the art. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991); *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984); *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983); *In re Clemens*, 622 F.2d 1029, 1035 (CCPA 1980); *In re Freeman*, 474 F.2d 1318, 1324 (CCPA 1973); *In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972).

On page 8 of the Brief, Appellants incorrectly state that such a small variation in size (50 microns versus 40 microns) would remain "free-flowing" and that therefore the Declaration supports the claimed range, but arguments of counsel cannot take the place of factually supported objective evidence. *See, e.g., In re Huang*, 100 F.3d 135, 139-40 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

In view of the above, we affirm the rejection.

3. The Rejection of claims 18-24, 26-44 and 47-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Schmidt '435 in combination with Schmidt '143 and Rawlins or Rawlins in view of Schmidt '435 or Schmidt '143 by themselves or in combination, further in view of Drake.

Appellants essentially rely on the same arguments used in the previous rejection and state that Drake does not cure the alleged deficiencies of the other applied art.

Hence, for the same reasons that we affirmed the previous rejection, we affirm this rejection also.

With respect to Appellants' arguments that Drake does not teach to use corn starch to improve stability of fat soluble molecules or how such stability can be improved while maintaining the free flowability of fat soluble molecules, we note that "[a]s long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor." *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992). The Examiner's reasons for combining Drake with the other references are sufficient.

In view of the above, we affirm the rejection.

CONCLUSIONS OF LAW AND DECISION

Appellants have not shown error in the Examiner's rejections, and we therefore affirm each rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(v).

AFFIRMED

cam

K & L GATES LLP
210 SIXTH AVENUE
PITTSBURGH, PA 15222-2613